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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,988	07/25/2005	Dieter Schamweber	17P21PCT/US	3213
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GUDRUN E. HUCKETT DRAUDT SCHUBERTSTR. 15A WUPPERTAL, 42289 GERMANY			EXAMINER KIM, YOUNG J	
			ART UNIT	PAPER NUMBER
			1637	
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			08/28/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,988	<b>Applicant(s)</b> SCHARNWEBER ET AL.	
	<b>Examiner</b> Young J. Kim	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23-44 is/are pending in the application.
- 4a) Of the above claim(s) 37-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I, consisting of claims 23-36 in the reply filed on August 3, 2007 is acknowledged. The traversal is on the ground(s) that the restriction practice was not in accordance with provisions set forth for a National Phase Application filed under 35 U.S.C. 371 (unity of invention practice).

Applicants' observation is correct. The present examiner apologizes for restricting the application according to the U.S. practice as provided under 35 U.S.C. 121.

It appears that so as to facilitate prosecution of the application, Applicants have elected Group I, consisting of claims 23-36. In an effort to do the same, the present Examiner has carefully reviewed Applicants' arguments produced with respect to the restriction practice. However, it is respectfully submitted that even with accordance with the unity of invention practice, the application fails to achieve the required unity of invention to preserve prosecution of different inventions in a single application.

The basis for finding the lack of unity of invention is provided below as well as rebuttal to Applicants' arguments produced in the response received on August 3, 2007.

#### **Lack of Unity of Invention:**

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 23-36, drawn to an object comprising a thin metal oxide layer and nucleic acid compounds incorporated thereto.

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Group II, claim(s) 37-40, drawn to a method of manufacturing a metallic object comprising a coating that is comprised of thin metal oxide layer and nucleic acid compounds.

Group III, claim(s) 41-44, drawn to a method of immobilizing complementary nucleic acid compounds.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

With regard to Applicants' statement found on page 5-6, regarding the inventions belonging to a single category of invention, it is respectfully submitted that the statement is not entirely correct. The instant application discloses three invention, the first being a product, and the second and the third being methods of producing said product. 37 CFR 1.475 provides for a category of invention for a single product, a single method of making, and a single method of using. The inventions II and III are both drawn to two different methods of making a product, and it would appear that the methods are different since the method of Inventions II and III employ a non-overlapping pH conditions.

In addition, even if, *arguendo*, that the inventions belonged to a single category of invention, such belonging does not necessarily preclude a finding of lack of unity.

PCT Rule 13.2, which defines the circumstances when the requirement for unity of invention is met, discloses that such would be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding *special technical features*. The same section defines *special technical feature* as a feature which defines a contribution which of each of the claimed inventions, considered as a whole makes over the prior art.

The shared special technical feature among the three inventions is in the physical attributes of the product itself. This attribute is the only feature that links the three inventions together, as the

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product itself does not recite any of the method steps involved in its production. While a method of producing a product may contribute over the prior art, it does not necessarily mean that the product produced by said method is also distinguished from a prior art product.

The specification discloses that the object comprising a thin metal oxide layer had been known in the art, but its production has been difficult (see pages 2-3). In addition, the holding of the instantly prosecuted claims obvious over prior art (as discussed below in the body of the Office Action) clearly relays that the special technical feature lacks novelty and obvious over prior art.

Therefore, the special technical feature which links the three inventions lacks novelty or is deemed obvious in view of the prior art. The unity of invention, as a result, does not exist.

Lastly, Applicants refer to a WIPO document which was referred to in the Office Action. The application file, including the most recent Office Action does not refer to any WIPO documents. Clarification is requested.

The requirement is still deemed proper and is therefore made FINAL.

Applicants are advised to leave the canceled method claims in “withdrawn” status, as the invention elected for prosecution is drawn to a product, and qualifies for rejoinder under *In re Ochiai*.

Upon allowance of the elected product, all method claims that are commensurate in scope of the allowed product claims will be rejoined as a matter of right. To preserve the right of rejoinder, Applicants **must** amend the withdrawn claims during the prosecution, so as to keep them commensurate in scope of the elected invention being examined. Failure to do so, will result in the loss of right to rejoinder.

Claims 37-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 3, 2007.

***Drawings***

The drawing received on January 4, 2005 is acceptable.

***Information Disclosure Statement***

No IDS has been filed to date of the instant Office communication.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 recites the term, “freely accessible to a large extent.” The metes and bounds of the underlined phrase is indeterminable. It would appear the deletion of the phrase, “to a large extent” would render the claim definite.

Claim 26 recites the phrase, “inorganic groups are selected from the groups consisting of.”

There is only one Markush group in this claim. The underlined word, “groups” should be changed to a singular form, “group.”

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 23-30, 32, 33, 35, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Bitner, R.M. (EP 0 391 608 A2, published October 10, 1990).

Bitner discloses a solid support comprising an amount of metal oxide (thus metallic object comprising a coating that is comprised of thin metal oxide layer; see page 3, line 20; page 4, line 16; page 7, lines 15-16), and nucleic acid molecules having their 5'- terminal or 3'- terminal ends incorporated into said metal oxide layer (page 3, lines 22-23), clearly anticipating claim 23.

With regard to claim 24, the nucleic acids retain their biological accessibility and reactivity, such as for hybridization (page 5, lines 10-13).

With regard to claims 25 and 26, the artisan discloses that the phosphate backbones of DNA molecules play a significant role in the sorption of the DNA molecules (page 5, lines 32-33).

With regard to claims 27 and 28, the metal of the metallic object is disclosed as being aluminum, titanium oxide, and zirconium oxide (page 4, lines 55-58).

With regard to claim 29, while the claim further limits its parent claim 28, in that it further describes one of the members of the Markush group of said claim 28, claim 29 does not actively require that the metal is actually an intermetallic phase.

With regard to claims 30 and 32, the nucleic acid is single- or double- stranded DNA or RNA, or oligonucleotides (page 5, lines 29-30).

With regard to claims 35 and 36, the artisan discloses the labeling the hybridized DNA molecules (page 8, lines 30-41; page 10, line 57).

Therefore, the invention as claimed is clearly anticipated by Bitner.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bitner, R.M. (EP 0 391 608 A2, published October 10, 1990) in view of Wengel et al. (U.S. Patent No. 6,670,461, issued December 30, 2003, filed on May 9, 2001).

The teachings of Bitner have already been discussed above.

Bitner does not disclose the use of nucleic acid compounds that have modification made thereto.

Wengel et al. disclose locked nucleic acids (LNA) which comprises ????? used in a diagnostic assay for detecting target nucleic acids with LNA probes via hybridization (column 2, lines 42-52).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bitner and the teachings of Wengel et al., thereby arriving at the claimed invention for the following reasons.

While Bitner does not explicitly disclose the use of other forms of nucleotide analogs which could be used as probes, one of ordinary skill in the art at the time the invention was made would have recognized that the advantage offered by LNA would have benefited said one of ordinary skill in the art to allow more stringent hybridization conditions, so as to preclude false positives in a hybridization assay of Bitner et al. The desire to increase stringency, as evidenced by Wengel et al., has been well-established in the art of nucleic acid hybridization detection. Hence, one of ordinary skill in the art would have been motivated to employ LNA nucleoside analogs into the immobilized nucleic acids of Bitner, thereby arriving at the invention as claimed.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.



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Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bitner, R.M. (EP 0 391 608 A2, published October 10, 1990) in view of Yabusaki et al. (WO 85/02628, published June 20, 1985).

The teachings of Bitner have already been discussed above.

Bitner does not disclose the hybridized nucleic acids are covalently bonded to the immobilized nucleic acids.

Yabusaki et al. disclose a method of forming covalent bonds between two hybridized nucleic acids by employing a nucleic acid which comprises cross-linking molecule that is covalently incorporated (page 3, lines 28-31; Abstract; page 32, lines 13-15).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to employ the teachings of Bitner with the teachings of Yabusaki et al., thereby arriving at the claimed invention for the following reasons.

One of ordinary skill in the art, at the time the invention was made would have recognized that the formation of covalent bonds between the two hybridized nucleic acids would have allowed for stringent wash conditions so as to minimize false positive results in their hybridization assay, by forming a covalent bond between the immobilized nucleic acid and the hybridized nucleic acid of Bitner, thereby arriving at the claimed invention.

One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success at combining the teachings given the fact that Yabusaki et al. employs the formation of covalent bonds between a probe and a target nucleic acid for the purpose of detection, demonstrating that cross-linking (for the formation of covalent bonds) could be made in solution, the condition of which is also used by Bitner.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

### ***Conclusion***

No claims are allowed.

### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

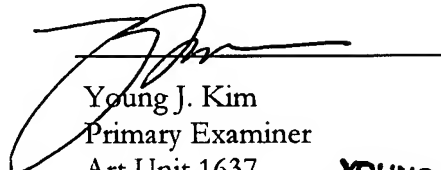
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like

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assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Young J. Kim  
Primary Examiner  
Art Unit 1637  
8/22/2007

**YOUNG J. KIM  
PRIMARY EXAMINER**

YJK